

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anti-Infective Drugs Advisory Committee and Nonprescription Drugs Advisory Committee

DoubleTree by Hilton Washington DC/Silver Spring

8727 Colesville Road, Silver Spring, Maryland

April 2, 2012

DRAFT AGENDA

The committees will provide advice on types of consumer studies needed to assess proper use of a MedKit containing doxycycline to be taken in the event of anthrax exposure. Issues such as the feasibility of an FDA-approved MedKit as a public health strategy, the role of personal MedKits, home stockpiling, and interfaces of home readiness with public health systems, will be raised in the course of the discussions. The Biomedical Advanced Research and Development Authority will propose a possible plan for a step-wise development program for MedKits containing oral doxycycline hyclate.

8:00 a.m.	Call to Order and Introduction of Committees	Thomas A. Moore, M.D., FACP Committee Chairperson, Anti-Infective Drugs Advisory Committee (AIDAC)
	Conflict of Interest Statement	Minh Doan, Pharm.D. Designated Federal Officer, AIDAC CDER, FDA
8:10 a.m.	<u>FDA Presentations</u> Doxycycline MedKit Regulatory Background	John Alexander, M.D., M.P.H. Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP), Office of New Drugs (OND), CDER, FDA
8:25 a.m.	Overview of Consumer Studies Potentially Applicable to the MedKit Development Program	Barbara Cohen, M.P.A. Social Science Analyst Division of Nonprescription Clinical Evaluation Office of Drug Evaluation IV (ODE IV) OND, CDER, FDA
8:40 a.m.	<u>Centers for Disease Control and Prevention Presentation</u> Emergency MedKit Evaluation	Linda J. Neff, Ph.D., M.S.P.H. (presenting via phone) Senior Epidemiologist Career Epidemiology Field Office Office of Science and Public Health Practice Office of Public Health Preparedness and Response Centers for Disease Control and Prevention

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DRAFT AGENDA (cont.)

8:55 a.m. Questions and Clarifications

Minnesota Department of Health Presentation

9:05 a.m. Home MedKits for Volunteer Postal
Workers in a Cities Readiness Initiative
Plan: A Minnesota Perspective

Ruth Lynfield, M.D.

State Epidemiologist and Medical Director
Minnesota Department of Health

Department of Homeland Security Presentation

9:20 a.m. Anthrax: An Enduring Terrorist Threat to
the Homeland

Susan Collier-Monarez, Ph.D.

Threat Characterization and Attribution
Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
Department of Homeland Security

Sponsor's Presentation

9:35 a.m. Doxycycline Medkits for Public Health
Preparedness for an Anthrax Attack

Biomedical Advanced Research and Development Authority

George W. Korch, Jr., Ph.D.

Senior Science Advisor
Office of the Assistant Secretary for
Preparedness and Response
Department of Health and Human Services

10:20 a.m. Questions and Clarifications

10:35 a.m. **BREAK**

Associations' Presentations

10:50 a.m. Prepositioning Antibiotics for Anthrax

Robert R. Bass, M.D., FACEP

Executive Director
Maryland Institute for Emergency Medical
Services Systems
Chair, Committee on Prepositioned Medical
Countermeasures for the Public
Institute of Medicine

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DRAFT AGENDA (cont.)

Associations' Presentations (cont.)

11:05 a.m.	Perspective of the Infectious Diseases Society of America	Andrew T. Pavia, M.D., FAAP, FIDSA George and Esther Gross Presidential Professor and Chief, Division of Pediatric Infectious Diseases University of Utah Member, Board of Directors and Chair, Pandemic Influenza and Bioemergencies Task Force Infectious Diseases Society of America
11:10 a.m.	Local Health Department Perspectives on MedKits	Jack Herrmann, M.S.Ed., N.C.C. Senior Advisor & Chief Public Health Preparedness National Association of County and City Health Officials
11:15 a.m.	State Public Health's Perspective on Medkits	James S. Blumenstock Chief Program Officer Public Health Practice Association of State and Territorial Health Officials
11:20 a.m.	Observations on Countermeasures for Anthrax	James J. James, M.D., Dr.P.H. Director, Center for Public Health Preparedness and Disaster Response American Medical Association
11:25 a.m.	Best Practices for Distribution of Doxycycline: Public Health Impact and Research Recommendations	Christopher J. Topoleski Director, Federal Regulatory Affairs American Society of Health-System Pharmacists
11:30 a.m.	American Pharmacist Association Comments on MedKits for Anthrax Exposure	Marcie Bough, Pharm.D. Senior Director, Government Affairs American Pharmacist Association
11:35 a.m.	The American Academy of Pediatrics Perspective on Stockpiling MedKits to be used for Children as Anthrax Post-Exposure Prophylaxis with Doxycycline	John Bradley, M.D. Director, Division of Infectious Diseases Rady Children's Hospital San Diego Member, Anthrax Working Group, Disaster Planning Advisory Council American Academy of Pediatrics

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DRAFT AGENDA (cont.)

11:40 a.m.	Questions and Clarifications
12:00 p.m.	LUNCH
1:00 p.m.	Open Public Hearing
2:00 p.m.	Charge to the Committees and Committees Discussion
3:00 p.m.	BREAK
3:15 p.m.	Charge to the Committees and Committees Discussion (cont.)
5:00 p.m.	ADJOURN